No. 96-1405

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,

Petitioner,

v.

SARAH KERNATS, a minor, by CYNTHIA KERNATS, her mother and next friend, CYNTHIA KERNATS, individually, and ANDREW KERNATS,

Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,

Petitioner,

v.

JOYCE OSHODI, individually and as mother and next friend of KENNETH OSHODI, a minor,

Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,

Petitioner,

v.

MARY SUSAN WILLIAMS, as mother and next friend of JOHN CALVIN WILLIAMS, a minor,

Respondents.

On Petition for Writ of Certiorari to the Appellate Court of Illinois, First District

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SUPPLEMENTAL BRIEF IN RESPONSE TO THE BRIEF OF THE UNITED STATES AS AMICUS CURIAE

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SUPPLEMENTAL BRIEF IN RESPONSE TO THE BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

Petitioner, Smiths Industries Medical Systems, Inc. ("SIMS"), respectfully submits this Supplemental Brief in Response to the Brief for the United States as Amicus Curiae.

I. THE RAPIDLY GROWING CONFLICT AMONG THE LOWER COURTS REGARDING MDA PREEMPTION DEMANDS IMMEDIATE INTERVENTION BY THIS COURT.

The Government grievously understates the growing conflict among the lower courts regarding MDA preemption as it pertains to Class III PMA and IDE medical devices. Significant questions left unanswered in *Medtronic, Inc. v. Lohr* have spawned a startling proliferation of conflicting decisions by State and Federal courts. During the eight months that have elapsed since SIMS filed its Reply Brief in support of the instant Petition, numerous State and Federal courts have reached disparate results in cases involving Class III PMA and IDE devices.

The full scope of judicial conflict—which involves cases too numerous to mention here—is reflected in the charts contained in the attached Appendix. The attached charts illustrate the division of authority in cases involving Class III PMA devices (App. 1), and also in cases involving Class III IDE devices (App. 2). A third chart illustrates the significant conflict among the lower courts as to whether MDA preemption applies to "generally applicable" state law tort claims (App. 3).

The recent decision of the United States Court of Appeals for the Seventh Circuit in *Mitchell v. Collagen Corporation,* 126 F.3d 902 (7th Cir., Sept. 23, 1997), exemplifies the difficulty the lower courts have experienced in attempting to apply *Medtronic* to cases involving Class III PMA and IDE devices. In *Mitchell,* a case involving a Class III PMA medical device, the court stated that "the holding in *Medtronic* contains several ambiguities that impair our ability to perceive with absolute clarity the path that the court has chosen for us to follow." *Id.* at 910.

The sharp division among the lower courts will continue to intensify unless this Court clarifies the "several ambiguities" of the *Medtronic* holding. As stated previously, the instant Petition raises questions regarding the preemptive effect of both the IDE *and* the PMA processes. The instant Petition therefore presents an extraordinary opportunity for this Court to answer conclusively *all* of the questions that have caused the rapidly growing judicial conflict.

II. THE ILLINOIS APPELLATE COURT'S DECISION IN *KERNATS* IS A "FINAL JUDGMENT" GIVING RISE TO JURISDICTION UNDER 28 U.S.C. § 1257.

Contrary to the Government's argument, this Court has jurisdiction to review the *Kernats* decision by way of the fourth exception to the "strict finality" rule outlined in *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469 (1975). The Government contends that this case does not fall within the fourth *Cox* exception because (1) the *Kernats* decision was entered by the Illinois Appellate Court rather than the Illinois Supreme Court (Brief of the United States at 11-12), and (2) a denial of the instant Petition will not risk eroding federal policy (Brief for the United States at 12-13). The Government is wrong in both respects.

The plain language of 28 U.S.C. § 1257 permits Supreme Court review of a final judgment "rendered by the highest court of a State in which a decision *could be had*". In this case, SIMS petitioned the Illinois Supreme Court for discretionary review of the Appellate Court's decision in *Kernats*, but that petition was denied. SIMS therefore exhausted its remedies within the State Court system. As a result, the Appellate Court's decision in *Kernats* constituted the judgment of the highest court in Illinois "in which a decision *could be had*".

This Court's decision in *Organization for a Better Austin v. Keefe*, 402 U.S. 415 (1971), effectively disposes of the Government's argument. In *Keefe*, the petitioner sought this Court's review of a decision of the Illinois Appellate Court after the Illinois Supreme court denied discretionary review of that judgment. *Id.* at 417-18. Thus, the procedural posture of the case in *Keefe* was iden-

tical to this case. Significantly, this Court found jurisdiction to be present, despite the fact that the lone dissenting Justice raised the same objection to jurisdiction as the Government advances here. Id. at 422-23. This Court has similarly found jurisdiction to exist in other cases where the judgment sought to be reviewed was reviewable by a higher state court, but such review was dependent upon the court's discretion. *See, e.g., Nash v. Florida Industrial Commission*, 389 U.S. 235 (1967), and *Local 174, Teamsters Union v. Lucas Flour Co.*, 369 U.S. 95 (1962).

The Government contends that allowing Plaintiffs' tort suits to proceed will not erode the congressional goal of the MDA to protect consumers and promote public health. (Brief of the United States at 13). SIMS does not deny that one of the purposes of the MDA is to protect consumers against unsafe medical devices. However, Congress *also* enacted the MDA in order to encourage the research and development of "sophisticated, critically important medical devices" which "hold the promise of improving the health and longevity of the American people." S. Rep. No. 94-33, 94th Cong., 2d Sess. (1976), *reprinted in* U.S.Code Cong. & Admin. News 1070, 1071. Within the MDA itself, in the section applicable to Class III IDE devices, Congress announced its purpose as follows:

> It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

21 U.S.C. § 360j(g)(1). Thus, the language of the MDA as well as its legislative history reflects a clear federal policy to encourage the advancement of medical device technology in order to serve the overriding purpose of the MDA—promoting the health of the American public.

The Government contends that the federal policy set forth above will not be jeopardized by allowing tort claims to proceed against the manufacturers of Class III PMA and IDE devices. However, the

United States Courts of Appeals, and also the American Medical Association, have taken a different position. The Sixth Circuit Court of Appeals in *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997), held that allowing tort claims to proceed against the manufacturers of Class III IDE medical devices would "thwart" the "twin aims" of the IDE regulations to promote safety and innovation. *Id.* at 1099. In *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, (7th Cir. 1992), the Seventh Circuit held that allowing product liability claims to proceed against an IDE device manufacturer "sets up a *direct collision with federal policy*". *Id.* at 1333. (emphasis added). And as previously stated in SIMS Petition, the American Medical Association Board of Trustees concluded in a 1988 report that product liability suits have had "a profound negative impact" on the development and availability of new medical technologies.[1]

The Government's argument that no federal policy is at risk is meritless. The federal policy underlying the MDA includes the goal of promoting public health by encouraging the development of new medical device technology. Absent the protection of MDA preemption, manufacturers of innovative medical devices may withdraw presently available devices from the market or choose not to develop new technology. As a necessary result, the health of the American public will suffer and the federal policy underlying the MDA will be eroded. Thus, the facts involved in this case fall squarely within the fourth *Cox* exception.

This Petition, for jurisdiction purposes, is also analogous to this Court's decision in *Mercantile National Bank at Dallas v. Langdeau*, 37 U.S. 555 (1963). Here, as in *Langdeau*, the judgment sought to be reviewed "is a separate and independent matter, anterior to the merits and not enmeshed in the factual and legal issues comprising the plaintiff's cause of action." 371 U.S. at 558. This is true given the fact that the issue of MDA preemption is unrelated to the merits

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[1] AMA, Report of Board of Trustees: Impact of Product Liability on the Development of New Medical Device Technologies. (June 1988).

of Plaintiffs' state law product liability claims. Furthermore, as in *Langdeau*, granting the instant Petition would serve "the policy underlying the requirement of finality in 28 U.S.C. §1257" by deciding the federal question at this time rather than subject SIMS, and Plaintiffs, to a "long and complex litigation which may all be for naught." *Id.* This is true given the fact that a reversal of the Illinois Appellate Court would preclude the need for *three separate* complex product liability actions (since this Petition involves three cases consolidated for appeal).[2]

Finding a jurisdictional basis in this case would also be consistent with this Court's prior findings of jurisdiction in cases where the federal question at issue involved the preemption of state law by federal law, and thus gave rise to important issues under the Supremacy Clause of the United States Constitution. *See, e.g., Local No. 438 Construction & General Laborers' Union v. Curry,* 371 U.S. 542 (1963); *Southland Corp. v. Keating,* 465 U.S. 1 (1984); *Mississippi Power & Light Co. v. Mississippi,* 487 U.S. 354 (1988); *Goodyear Atomic Corp. v. Miller,* 486 U.S. 174 (1988).

A final consideration warranting a finding of jurisdiction arises from the nature of the initial trial court rulings that found in favor of preemption and granted SIMS' motion for summary judgment. In each of the three cases underlying this consolidated appeal, the trial court made an express finding that its decision granting summary judgment was "final and appealable" pursuant to Illinois Supreme Court Rule 304(a). Illinois Supreme Court Rule 304(a) is the state law equivalent of Federal Rule of Civil Procedure 54(b), which permits decisions made by Federal District Courts affecting a single party in a multi-party claim to be immediately appealed. In the view of authoritative commentators, judgments made pursuant to state

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[2] All three cases have been stayed in the Circuit Court of Cook County pending the resolution of the instant Petition.

law equivalents of Rule 54(b) should be appealable to the United States Supreme Court.[3]

III. THE GOVERNMENT'S VIEW CONFLICTS WITH THE LEGISLATIVE PURPOSE OF THE MDA'S PREEMPTION PROVISION AS WELL AS THIS COURT'S DECISION IN *MEDTRONIC*.

The Government contends that the Illinois Appellate Court in *Kemats* correctly concluded that the MDA does not preempt Plaintiffs' claims. In its Petition and Reply Brief, SIMS explained the reasons why the *Kemats* decision should be reversed. SIMS will not restate those arguments here, but will address the flaws in the arguments asserted by the Government in its amicus brief.

The Government contends that the requirements imposed under the PMA and IDE processes are not sufficiently specific to trigger preemption. (Brief of United States at 14). In numerous cases decided before and after this Court's decision in *Medtronic*, the same argument has been rejected by Federal Appellate Courts and State Supreme Courts. *See e.g., Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997) (IDE requirements sufficiently specific); *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I. S.Ct. 1997) (PMA requirements sufficiently specific); *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir. 1993) (PMA); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (PMA).

The Government contends that IDE and PMA approval of a medical device merely reflects a determination that the medical device has met certain "minimal standards for use and marketing". (Brief of United States at 14). Here, the Government understates the nature and extent of the FDA's PMA and IDE review processes. In

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[3] "If finality is achieved within a state court system by a rule [comparable to Fed.Civ.Pro. 54(b)], there is no reason to insist on a 'complete judicial unit' theory of finality. To the contrary, there is every reason to cooperate with the state attempt to achieve finality. State court review should be followed by Supreme Court review, then or never." Charles Alan Wright, Arthur R. Miller, and Edward H. Cooper, *Federal Practice and Procedure*, Chapter 10, §4010, p. 198 (2nd Ed. 1996).

Medtronic, this Court described at length the extensiveness of the PMA process, as contrasted with the cursory nature of the 510(k) premarket notification process. *Medtronic*, 116 S.Ct. at 2246-47. As set forth in SIMS' Petition, the IDE process is even more rigorous than the PMA process. (SIMS Petition at 13-14).

The approval of a medical device under the PMA process does not merely signify that device has satisfied routine administrative requirements prior to its distribution. Rather, FDA approval under the PMA process reflects a specific federal determination, made only after intense scrutiny of the device itself and of detailed information regarding its clinical use, that the device is safe and effective. 21 U.S.C. § 360e(d)(2). Approval under the IDE process reflects a similar determination regarding the safety of a particular medical device. 21 C.F.R. §812.30. The Government's characterization of PMA and IDE approval as an administrative "rubber-stamp"—made with little regard for safety and efficacy—is grossly misleading.

The Government's interpretation of MDA preemption establishes virtually unattainable requirements that effectively eviscerate the intended function of the MDA's express preemption provision. The Government contends that preemption should occur only when the FDA promulgates a regulation that (1) is specifically applicable tc a particular medical device, and (2) is separate from, and in addition to, the requirements of the PMA or IDE processes. (Brief of the United States at 15). The Government states that the FDA promulgates such regulations only in "extraordinary" circumstances. Significantly, the Government fails to identify *any* circumstance where the FDA has *ever* promulgated such a preemption-triggering regulation. Recognition of that fact raises serious doubts whether the FDA will ever promulgate a preemption-triggering regulation.

The Government also contends that preemption applies only to state law tort claims that impose "substantive requirements specifically with respect to" a particular medical device. Here, the Government seems to contemplate a state common law duty geared specifically towards a particular medical device. In reality, however,

all state law product liability claims arise from common law duties that apply to every product manufacturer. Those common law duties do not apply specifically to a particular class of devices, much less a particular medical device. Thus, the Government's interpretation of MDA preemption proposes still another requirement which, in all probability, will never be met.

Congress specifically included an express preemption provision within the MDA. Therefore, this Court must infer that Congress intended the preemption provision to actually serve a purpose. A majority of this Court's Justices in *Medtronic* held that the MDA's preemption provision should operate to preempt common claims in circumstances far less extraordinary, and far less improbable, than those described by the Government in its amicus brief. Justices O'Connor, Rehnquist, Scalia and Thomas held in *Medtronic* that certain of the Plaintiffs' manufacturing and labeling claims were preempted by the MDA. 116 S.Ct. at 2264.[4] Justice Breyer specifically rejected the statement in the plurality opinion that "few, if any, common-law duties have been preempted by" the MDA. Rather, Justice Breyer held that "I am not convinced that future incidents of MDA preemption of common-law duties will be 'few' or 'rare' ". *Id.* at 2262.

The Government's interpretation of MDA preemption essentially posits a preemption provision that will rarely, if ever, be triggered. Such an interpretation of MDA preemption cannot be reconciled with the self-evident congressional intent that the MDA preemption provision actually serve a functional purpose. Nor can the Government's position be reconciled with the opinions expressed in *Medtronic* by Justices Breyer, O'Connor, Rehnquist, Scalia and Thomas.

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[4] The holding of the aforesaid dissenting Justices is particularly significant given the fact that the medical device at issue in *Medtronic* was subject only to the 510(k) premarket notification process, not to the more rigorous PMA or IDE processes.

IV. THE FDA'S PROPOSED INTERPRETIVE RULE WILL NOT RESOLVE THE CONFLICT AMONG THE LOWER COURTS.

The Government engages in unsupported speculation by contending that the FDA's proposed "interpretive rule" will resolve the conflict among the lower courts. Although this Court held in *Medtronic* that FDA preemption regulations are entitled to "substantial weight", this Court did *not* hold that courts are bound to defer to such regulations under the *Chevron* doctrine. *Medtronic*, 116 S.Ct. at 2256; *see also*, 116 S.Ct. at 2263 (O'CONNOR, J., with whom REHNQUIST, C.J., SCALIA, J., and THOMAS, J., join, concurring in part and dissenting in part). In future MDA preemption cases, courts are therefore free to reject the FDA's proposed interpretive rule.

Prior to *Medtronic*, numerous courts rejected FDA regulation § 808.1(d)(1) as an erroneous interpretation of § 360k(a) which is contrary to Congress' intent and therefore entitled to no deference.[5] In post-*Medtronic* decisions, several courts also have reached conclusions contrary to the FDA's preemption regulations. In *Papike v. Tambrands Inc.*, 107 F.3d 737, 741-42 (9th Cir. 1997), the Ninth Circuit held that the MDA preempted a failure to warn claim arising from "generally applicable" tort principles despite the fact that § 808.1(d)(1) provides that "State or local requirements of general applicability" are not preempted. In *Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997), the Seventh Circuit held that the MDA preempted an implied warranty claim, although § 808.1(d)(1) provides that preemption does not apply to claims based on an implied warranty of fitness.

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[5] *See, e.g., Mitchell v. Collagen Corp.*, 870 F.Supp. at 893 (N.D. Ind. 1994) (section 808.1(d)(1) is "contrary to the Congress's intent, as expressed in § 360k(a)"), *aff'd*, 67 F.3d 1268 (7th Cir. 1995), *cert. granted, judgment vacated and remanded for further consideration in light of Medtronic*, 116 S.Ct. 2576 (1996), *aff'd*, 126 F.3d 902 (7th Cir. 1997); *Talbott v. C.R. Bard, Inc.*, 865 F.Supp. at 49 (D.Mass. 1994) (section 808.1(d)(1) "conflicts with the clear expression of Congressional intent contained in 21 U.S.C. §360k(a)"), *aff'd*, 63 F.3d 25 (1st Cir. 1995).

Thus, despite the Government's hopeful expectations, the FDA's proposed interpretive rule provides scant assurance that the conflict among the lower courts will subside absent a conclusive decision issued by this Court. This is particularly true given the very real possibility that many lower courts will refuse to follow the FDA's interpretive rule based on its inherent flaws and its inconsistencies with the *Medtronic* decision.[6]

Additionally, the FDA's proposed interpretive rule will do *nothing* to remedy the division among the lower courts that exists today. In the wake of *Medtronic*, numerous Federal Appellate Courts and State Supreme Courts have reached conflicting results regarding MDA preemption. Those conflicting decisions will remain the "law of the land" regardless of the issuance of the FDA's proposed rule. Furthermore, under *stare decisis*, the subordinate Federal and State courts will be bound to follow the decisions of their "superior" courts regardless of the issuance of the FDA's proposed rule. Consequently, subordinate courts in one jurisdiction will continue to enter decisions that conflict with the decisions of subordinate courts in other jurisdictions.

The FDA's proposed rule will not resolve the current division among the lower courts. The *only* way the current conflict can be resolved is through the intervention of this Court. For if this Court were to grant the instant Petition and conclusively decide the MDA preemption issue as it pertains to Class III PMA and IDE medical devices, that decision would represent the *only* law of the land.

CONCLUSION

The petition for writ of certiorari should be granted.

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[6] The flaws and inconsistencies of the FDA's proposed rule are highlighted above in SIMS' criticism of the arguments contained in the Government's amicus brief, which arguments simply mirror the FDA's proposed rule.

Respectfully submitted,

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APPENDIX

PMA CASES	
PREEMPTION	**NO PREEMPTION**
Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 9/23/97)	*Lakie v. SmithKline Beecham*, 965 F.Supp. 49 (D.Columbia 3/5/97)
Fry v. Allergan Medical Optics, 695 A.2d 511 (R.I. S.Ct. 6/19/97)	*Hernandez v. Coopervision, Inc.*, 691 So.2d 639 (Fla. App. Ct. 4/18/97)
Green v. Dolsky, 685 A.2d 110 (Pa. S.Ct. 11/22/96)	*Sowell v. Bausch & Lomb, Inc.*, 230 AD.2d 77 (N.Y. App. Div. 4/10/97)
Easterling v. Cardiac Pacemakers, Inc., ___F.Supp.___ 1997 WL 732422 (E.D.La. 11/21/97)	*Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. Ct. App. 10/29/96)
Goodlin v. Medtronic, Inc., No. 97-6133-CIV (S.D.Fla. 10/29/97)	*Kernats v. Smiths Industries*, 669 N.E.2d 1300 (Ill. App. Ct. 9/3/96)
LeMay v. Eli Lilly & Co., 960 F. Supp. 183 (E.D.Wis. 4/9/97)	*Walker v. Johnson & Johnson*, 552 N.W.2d 679 (Mich. Ct. App. 7/26/96)
Steele v. Collagen Corp., 63 Cal. Rptr. 2d 879 (Cal. Ct. App. 5/15/97)	*Mears v. Marshall*, 944 P.2d 984 (Or. Ct. App. 9/10/97)
Milkiewicz v. Baxter Healthcare, 963 F. Supp. 1150 (M.D.Fla. 12/16/96)	

IDE CASES	
PREEMPTION	**NO PREEMPTION**
Chambers v. Osteonics Corp., 109 F.3d 1243 (7th Cir. 4/3/97)	*Niehoff v. Surgidev Corporation*, 95 S.W.2d (Ky. S.Ct. 6/19/97)
Martin v. Telectronics, 105 F.3d 1090 (6th Cir. 1/31/97)	*Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. S.Ct. 8/20/96)
Chmielewski v. Stryker Sales Corp., 966 F.Supp. 839 (D.Minn. 6/17/97)	*Baird v. American Medical Optics*, 693 A.2d 904 (N.J. App. Ct. 5/12/97)
Berish v. Smith & Nephew, 937 F. Supp. 181 (N.D.N.Y. 8/22/96)	*Shea v. Oscor Medical Corp.*, 950 F.Supp. 246 (N.D.Ill. 12/18/96)
	Kernats v. Smiths Industries, 669 N.E.2d 1300 (Ill. App. Ct. 9/3/96)

"GENERALLY APPLICABLE" STATE LAW CLAIMS	
PREEMPTED	**NOT PREEMPTED**
Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 9/23/97)	*Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 4/16/97)
Martin v. Telectronics, 105 F.3d 1090 (6th Cir. 1/31/97)	*Committee of Dental Amalgam Manufacturers & Distributors v. Stratton*, 92 F.3d 807 (9th Cir. 8/5/96)
Papike v. Tambrands, Inc., 107 F.3d 737 (9th Cir. 2/20/97), partially overruling *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995); conflicts with *Committee of Dental Amalgam*, (see opposite column)	*Niehoff v. Surgidev Corporation*, 95 S.W.2d 816 (Ky. S.Ct. 6/19/97)
Fry v. Allergan Medical Optics, 695 A.2d 511 (R.I. S.Ct. 6/19/97)	*Mears v. Marshall*, 944 P.2d 984 (Or. Ct. App. 1997)
Chmielewski v. Stryker Sales Corp., 966 F.Supp. 839 (D.Minn. 6/17/97)	*Headen v. Mentor Corporation*, 1997 WL 27104 (USDC E.D.Pa. 1/23/97)
Steele v. Collagen Corp., 63 Cal. Rptr.2d 879 (Cal. Ct. App. 5/15/97); conflicts with *Armstrong*, (see opposite column)	*Lakie v. Smith Kline Beecham*, 1997 WL 286209 (USDC D.C. 3/5/97)
	Baird v. American Medical Optics, 693 A.2d 904 (N.J. App. Ct. 5/12/97)
	Armstrong v. Optical Radiation Corp., 57 Cal. Rptr. 2d 763 (Cal. Ct. App. 10/29/96)
	Kernats v. Smiths Industries, 669 N.E.2d 1300 (Ill. App. Ct. 9/3/96)